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ART UNIT	PAPER NUMBER
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1804

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DATE MAILED: 04/01/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☒ Responsive to communication filed on 1/24/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 3 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-20 are pending in the application.

Of the above, claims 2-3 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1 and 4-20 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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Applicants' assertions in the IDS of 9 June 1993 regarding the availability of the Rohde et al. publication are noted. However, anecdotal allegations are not deemed probative. A declaration demonstrating the date of distribution should be submitted.

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the grounds that the search for Group I would encompass the search for Group II, that no restriction was made in the copending PCT application, and that restrictions in Rule 371 applications are improper as supported by case law. This is not found persuasive because the search for Group II requires the additional concepts of starch extraction and chemical treatment ("derivation") not required by the search for Group I, as stated in the last office action. With regard to PCT practice, the failure of the Examiner to restrict in the PCT does not prohibit the Examiner in the U.S. case from restricting, since restriction is at the discretion of the individual Examiner. With regard to the cited case law, the Examiner maintains that the case law teaches that the criteria for restriction under U.S. practice and PCT practice may differ, but does not unilaterally prohibit restriction of Rule 371 cases. The instant restriction was set forth as involving two distinct products which each required separate special technical features, as is appropriate for restriction under PCT practice.

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The requirement is still deemed proper and is therefore made FINAL.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 5-6 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to non-isolated promoters and genes, and as such read on naturally occurring promoters and genes found in the genome of naturally occurring potato plants. The DNA molecules, as claimed, have the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore do not constitute patentable subject matter. See American Wood v. Fiber Distintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brogdex Co., 283 U.S. 2 (1931), Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948), Diamond v. Chakrabarty, 206 USPQ 193 (1980).

Claims 1 and 4-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 4-8 and 10, and claims 9 and 11-20 (dependent thereon), are indefinite in their recitation of "essentially" which fails to adequately characterize the degree of similarity between the claimed DNA sequences and the Seq. ID

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Nos. or the length of the claimed sequences, and so fails to adequately characterize the claimed DNA sequences. Claims 1, 4, 7 and 9-10, and claims 8 and 11-20 (dependent thereon), are indefinite for failing to employ proper Markush terminology. See M.P.E.P. 706.03(y). Claims 4-7 and 10, and claims 8-9 and 11-20 (dependent thereon), are indefinite in their recitation of "in potato" as it is unclear whether this refers to the expression of any gene once it is inserted into potato, or whether this refers to a gene whose source is potato (as implied in claim 1 by the recitation of "potato gene"). Claim 10 is indefinite in its recitation of "antisense orientation" since the claim is merely drawn to a vector comprising a DNA fragment inserted therein, wherein antisense orientation would be defined by being relative to something else present on the vector, e. g. a promoter immediately upstream from the DNA fragment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5-6 are rejected under 35 U.S.C. § 102(a) or 102(b) as being anticipated by Rohde et al. Rohde et al. teach a potato GBSS promoter with a sequence which corresponds "essentially" to the claimed sequence (see, e. g., page 313, Figure 1B). Rohde et al. also teach two genomic clones containing the structural gene

(see, e. g., page 313, Figure 1A), wherein the gene on each of the clones has a sequence that is an inherent property of the gene obtainable by routine sequencing techniques, wherein the sequence would correspond "essentially" to the claimed sequence.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 5-6 are rejected under 35 U.S.C. § 102(a) as being anticipated by van der Liej et al. Van der Liej et al. teach the sequences of the potato GBSS gene and promoter (see, e. g., page 243), wherein these sequences correspond "essentially" to those claimed.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 5-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Visser. Visser teaches full length genomic clones of the potato GBSS gene which would inherently include the promoter, wherein the gene is expressed in potato tissue, indicating the presence of an active promoter in the native plants (see, e. g., pages 88-94). The gene on each of the clones has a sequence that is an inherent property of the gene obtainable by routine sequencing techniques, wherein the sequence would correspond "essentially" to the claimed sequence.

Claims 5-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Visser et al. (1989). Visser et al. (1989) teach full length genomic clones of the potato GBSS gene which would

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inherently include the promoter, wherein the gene is expressed in potato tissue, indicating the presence of an active promoter in the native plants (see, e. g., pages 188-190). The gene on each of the clones has a sequence that is an inherent property of the gene obtainable by routine sequencing techniques, wherein the sequence would correspond "essentially" to the claimed sequence.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 14, 16 and 20 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Hovenkamp-Hermelink et al. Hovenkamp-Hermelink

et al. teach amylose-free potato tubers (see, e. g., page 219) which are the result of the inactivation of the GBSS gene (see, e. g., page 220, column 2, first full paragraph). The potato tubers taught by the reference differ from the claimed potato tubers in the lack of an antisense construct. However, the presence of an antisense construct does not appear to distinguish the amylose-free, GBSS-inactivated tubers taught by the reference from the claimed tubers. See M.P.E.P. 706.03(e). Thus, the claimed invention was at least clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Hovenkamp-Hermelink et al.

Claims 13-15 and 19-20 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Cochran. Cochran teaches potato plants, tubers and seeds (see, e. g., column 4, Table I). The plants, tubers and seeds differ from the claimed products in the lack of an antisense DNA construct. However, the presence of a DNA construct does not appear to distinguish the claimed tubers and plants from those taught by the reference, particularly in view of the lack of appreciable change in starch composition following the transformation of potato plants with the potato GBSS gene in antisense orientation by other workers (see, e. g., pages 4-5 of the instant specification), and in view of the lack of any demonstration in the instant specification regarding the composition of the starch from transformed plants. See M.P.E.P.

706.03(e). Thus, the claimed invention was at least clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Cochran.

Claim 16 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Twell et al. Twell et al. teaches microtubers (see, e. g., page 368, column 1, first full paragraph). The microtubers differ from the claimed products in the lack of an antisense DNA construct. However, the presence of a DNA construct does not appear to distinguish the claimed microtubers from those taught by the reference, particularly in view of the lack of appreciable change in starch composition following the transformation of potato plants with the potato GBSS gene in antisense orientation by other workers (see, e. g., pages 4-5 of the instant specification), and in view of the lack of any demonstration in the instant specification regarding the composition of the starch from transformed plants. See M.P.E.P. 706.03(e). Thus, the claimed invention was at least clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Twell et al.

Claims 1, 4, 7 and 9-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Visser. Visser teaches the transformation of a potato plant with a gene construct comprising the CaMV 35S promoter, the maize GBSS gene in antisense orientation, and the NOS terminator for the reduction of GBSS

activity and reduction of amylose production in tubers of transformed plants (see, e. g., pages 100, 105-107). Visser also teaches the isolation of the gene encoding potato GBSS (pages 88-94), and suggests the use of this gene for further investigation of inhibition of amylose production and for the production of new starches (see, e. g., page 122, bottom paragraph). Visser also teaches the in vitro production of tubers from tissue culture-derived shoots, wherein said tubers are currently designated as "microtubers" (see, e. g., page 93, Figure 3; page 102). Visser does not teach the transformation of a potato plant with the potato GBSS gene, either in complete form or in fragments, in antisense orientation for the inhibition of amylose production. It would have been obvious to one of ordinary skill in the art to utilize the method of antisense RNA-mediated reduction of amylose production in potato taught by Visser, and to modify that method by incorporating the potato GBSS gene taught by Visser or any restriction fragment thereof, given the recognition by those of ordinary skill in the art that the use of a native gene with increased homology would be more effective in antisense RNA-mediated gene inhibition, given the suggestion to do so by Visser, and given the recognition by those of ordinary skill in the art that choice of particular restriction fragment of the gene for insertion into a vector would have been the optimization of process parameters. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the

art at the time it was made, especially in the absence of evidence to the contrary.

Claims 8 and 17-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Visser as applied to claims 1, 4, 7 and 9-16 above, and further in view of Rohde et al. Visser teaches a potato plant containing a gene construct comprising a promoter and the potato GBSS gene in antisense orientation for the inhibition of amylose production as discussed supra, but does not teach the use of the potato GBSS promoter. Rohde et al. teach the use of the potato GBSS promoter to drive the expression of a heterologous gene at high levels in potato tubers (see, e. g., page 312, column 2, first full paragraph; page 313; page 314, Table 1). It would have been obvious to one of ordinary skill in the art to utilize the gene construct for inhibition of amylose activity taught by Visser and to modify that construct by incorporating the potato PGBSS promoter taught by Rohde et al., given the recognition by those of ordinary skill in the art that choice of promoter would have been the optimization of process parameters. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 8 and 16-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Visser as applied to claims 1, 4, 7 and 9-16 above, and further in view of Twell et al. Visser teaches a potato plant containing a gene construct comprising a promoter and the potato GBSS gene in antisense orientation for the inhibition of amylose production as discussed supra, but does not teach the use of the potato GBSS promoter. Twell et al. teach the identification of a promoter region 5' from the structural gene of a tuber-specific gene, the tuber-specific expression of a heterologous gene from this promoter, and the benefits of tuber-specific heterologous gene expression (see, e. g., page 366, column 1, second full paragraph; page 368, Figure 1; page 369; page 371). Twell et al. also teach the induction of microtubers for rapid evaluation of heterologous gene expression (see, e. g., page 368, column 1, first full paragraph). It would have been obvious to one of ordinary skill in the art to utilize the gene construct for inhibition of amylose activity taught by Visser and to modify that construct by incorporating the isolated potato PGBSS promoter from the genomic clone taught by Visser, wherein the promoter would have been identified and isolated by the techniques taught by Twell et al., as suggested by Twell et al., given the recognition by those of ordinary skill in the art that choice of promoter would have been the optimization of process parameters. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art at the

time it was made, especially in the absence of evidence to the contrary.

Claims 1, 4, 7 and 9-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Visser et al. (1991). Visser et al. (1991) teach the transformation of potato with an antisense construct comprising the CaMV 35S promoter and the potato GBSS gene in antisense orientation, wherein tubers were obtained which exhibited reduced amylose production (see, e. g., page 290; page 291, top paragraph; page 293, paragraph bridging columns 1 and 2). Visser et al. do not teach the use of the claimed restriction fragments of the potato GBSS gene in antisense orientation. It would have been obvious to one of ordinary skill in the art to utilize the method of antisense RNA-mediated amylose reduction taught by Visser et al. (1991), and to modify that method by incorporating a variety of restriction fragments of the gene taught by Visser et al. (1991) including the claimed fragments, given the recognition by those of ordinary skill in the art that choice of particular restriction fragment of the gene for insertion into a vector would have been the optimization of process parameters. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 8 and 16-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Visser et al. (1991) as applied to claims 1, 4, 7 and 9-15 above, and further in view of Twell et al. Visser et al. teach a potato plant containing a gene construct comprising a promoter and the potato GBSS gene in antisense orientation for the inhibition of amylose production as discussed supra, but do not teach the use of the potato GBSS promoter or the induction of microtubers. Twell et al. teach the identification of a promoter region 5' from the structural gene of a tuber-specific gene, the tuber-specific expression of a heterologous gene from this promoter, and the benefits of tuber-specific heterologous gene expression (see, e. g., page 366, column 1, second full paragraph; page 368, Figure 1; page 369; page 371). Twell et al. also teach the induction of microtubers for rapid evaluation of heterologous gene expression (see, e. g., page 368, column 1, first full paragraph). It would have been obvious to one of ordinary skill in the art to utilize the gene construct for inhibition of amylose activity taught by Visser et al. and to modify that construct by incorporating the isolated potato PGBSS promoter from the genomic clone taught by Visser et al., wherein the promoter would have been identified and isolated by the techniques taught by Twell et al., as suggested by Twell et al., given the recognition by those of ordinary skill in the art that choice of promoter would have been the optimization of process parameters. It also would have been obvious to modify

the procedure taught by Visser et al. (1991) by utilizing the microtuber technique taught by Twell et al., given the recognition by those of ordinary skill in the art of the desirability of speeding up the process for assaying foreign gene expression. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

Claims 8 and 17-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Visser et al. (1991) as applied to claims 1, 4, 7 and 9-15 above, and further in view of Rohde et al. Visser et al. teach a potato plant containing a gene construct comprising a promoter and the potato GBSS gene in antisense orientation for the inhibition of amylose production as discussed supra, but do not teach the use of the potato GBSS promoter. Rohde et al. teach the use of the potato GBSS promoter for heterologous gene expression as discussed supra. It would have been obvious to one of ordinary skill in the art to utilize the gene construct for inhibition of amylose activity taught by Visser et al. and to modify that construct by incorporating the isolated potato PGBSS promoter as taught by Rohde et al., given the recognition by those of ordinary skill in the art that choice of promoter would have been the optimization of process

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parameters. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a certified translation of said papers has not been made of record. See M.P.E.P. § 201.15.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 30, 1994

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180



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